K032039

SEP - 8 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is: _____.

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 Phone: (847) 996-4675; FAX: (847) 996-4693 Contact person: Nina Gamperling Date prepared: June 30, 2003
2. Name of Device:	Trade or proprietary name: Immature Granulocyte (IG) parameter on the Sysmex® XE-2100, Automated Hematology Analyzer. Common name: IG parameter Classification name: IG parameter on the Automated Differential Cell Counter, Sysmex® XE-2100 (21 CFR 864.5220)
3. Predicate Device:	The IG parameter on the Sysmex® XE-2100 is substantially equivalent to the microscopic method of the manual differential cell counting used in the United States prior to 1976.
4. Device Description:	The XE-2100 is an automated hematology analyzer previously cleared by the FDA. The Immature Granulocyte (IG) count is measured in the DIFF channel. The combination of side scatter, forward scatter, and fluorescent intensity of nucleated cells gives an image of each cell detected in the peripheral blood. Different leukocyte populations or clusters such as the immature granulocytes are counted by the XE-2100. (Note: XE-Pro and IG Master are required to obtain results described.)
5. Intended Use:	The Immature Granulocyte (IG) parameter on the Sysmex® XE-2100 is intended for *in Vitro* Diagnostic use to classify and count immature granulocyte cells in EDTA anti-coagulated blood.
6. Substantial equivalence-similarities and differences	The following table compares the IG parameter with predicate method.

Comparison Table to Predicate Method

	Manual Microscopic Differential Cell Count	**IG count on the XE-2100**
	Predicate	**New method**
Intended Use	To manually classify and count the white blood cells into sub categories using a microscope.	To classify and count immature granulocyte cells in EDTA anti-coagulated blood.
Methodology	Manual counting of immature granulocytes using a microscope. Typically the manual method counts 100 cells. The NCCLS H20-A method uses 400 cell differential performed by 2 techs each counting 200 cells.	Automated counting of immature granulocytes on an automated hematology analyzer.
Type of Anticoagulant	EDTA	EDTA
Specimen Type	Peripheral blood	Peripheral blood
Accuracy	Method of real counting of cells using a microscope established as the predicate method.	Comparison to manual count showed good correlation.
Pro/Con	Manual method is imprecise due to the small number of cells counted, typically not more than 100 WBC total. It is labor intensive and time-consuming.	A large number of cells can be analyzed and several parameters (i.e. forward scatter [FSC], side scatter [SSC], and fluorescent labels) rather than morphological appearance alone can be used.

7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the IG count to the predicate method. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 8 2003

Ms. Nina M. Gamperling, MBA, MT(ASCP), RAC
Manager, Regulatory Affairs
Sysmex America, Inc.
One Nelson C. White Parkway
Mundelein, IL 60060

Re: k032039
Trade/Device Name: Immature Granulocyte (IG) parameter on the Sysmex® XE-2100™, Automated Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: June 30, 2003
Received: July 9, 2003

Dear Ms. Gamperling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_____

Device Name: Immature Granulocyte (IG) parameter on the Sysmex® XE-2100™, Automated Hematology Analyzer

Indications For Use:

The Immature Granulocyte (IG) parameter on the Sysmex® XE-2100 is intended for *in Vitro* Diagnostics to classify and count immature granulocyte cells in EDTA anti-coagulated blood.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CHRD, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032039